

**REMARKS**

Claims 19 - 40 are presently pending in the current application. In light of the following remarks, it is respectfully submitted that these claims are in condition for allowance.

Claims 19 - 25, 27, 31, 34 - 38, and 40 stand rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,032,125 to Durham et al. in view of U.S. Patent No. 5,454,813 to Lawes.

Claim 19 recites a device for the treatment of femoral fractures comprising an intramedullary pin having “at least one transverse opening through the proximal portion...forming an oblique angle with the first longitudinal axis and having a non-circular cross-section” and “a bone fixation element having a...first end configured and dimensioned to engage bone in the femoral head” in combination with “a sliding sleeve having a central bore, an interior surface profile, and an exterior surface profile, *the central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve*, and the exterior surface profile having at least a portion with a non-circular cross-section adapted to mate with the non-circular cross-section of the transverse opening, thereby prevention rotation of the sleeve with respect to the intramedullary pin” and “*a locking mechanism configured and adapted to selectively lock rotation of the bone fixation element relative to the sleeve when in a first position and permit free rotation of the bone fixation element relative to the sleeve when in a second position.*”

It is respectfully submitted that Durham fails to teach or suggest a sliding sleeve with “a central bore and interior surface profile configured to receive the shaft of the bone fixation element *while permitting free rotation of the bone fixation element relative to the sleeve*,” as recited in claim 19. Rather, Durham shows a system with a sleeve 40 which is rotatable relative to the intramedullary rod 20 and a lag screw 60 which is keyed to an interior of the sleeve 40 to

prevent rotation of the lag screw 60 relative to the sleeve 40. (*See* Durham, col. 4, ll. 3 - 6; Fig. 1). This is the opposite of the claimed arrangement and necessitates an additional set screw 80 inserted longitudinally through the intramedullary rod 20 to engage a surface of the sleeve 40 and lock it against rotation after it has been properly positioned. (*See* Durham, col. 4, li. 58 - col. 5, li. 11; Fig. 1) The selection of the keyed surfaces of the lag screw 60 and the interior of the sleeve 40 of Durham are clearly more than mere design choices as they impact multiple steps in the procedure for implanting the system. Specifically, in contrast to the claimed apparatus, the lag screw 60 of Durham can not be inserted while received within the sleeve 40. (*Id.*). The lag screw 60 is first rotatably inserted through the intramedullary rod 20 to a desired position in the femur. The sleeve 40 is slid over a shaft of the lag screw 60 only after the lag screw 60 has been inserted to the desired position because if it were present during insertion of the lag screw 60, the lag screw 60 would not be able to rotate as required. The sleeve 40 is then locked in position by insertion of a set screw 80 longitudinally through the intramedullary rod 20 to engage ridges 50 formed on the sleeve 40. (*Id.*). The Examiner's proposed modification completely alters every one of these steps and is clearly far more than a mere design choice. None of these proposed changes is in any way described or suggested in Durham or in any of the other cited references and it is submitted that the Examiner's rejection is an improper hindsight reconstruction of the invention the only motivation for which is the disclosure of the present application.

In the Final Office Action, the Examiner also indicates that Durham only indicates "that the device may include engagement surfaces to perform the function if so desired, which means that the device does not have to include the engagement surfaces and therefore may not be included in the device." (*See* 11/18/08 Office Action, p. 8). The only support the Examiner has relied on for this assertion is the premise that the detailed description of Durham describes preferred embodiments only and does not describe every possible variation of the device. However, it is respectfully submitted that such flimsy support can not serve to justify structural changes to a system which require radical changes to the medical procedure required to use the system. Clearly any change to the method of use of a surgical implant is a significant change and

not, as the Examiner stated, a matter of mere design choice. It is therefore respectfully submitted that the modification proposed by the Examiner constitutes an improper hindsight reconstruction of the Durham and that this rejection should be withdrawn.

Lawes does not cure the above mentioned deficiencies of Durham. It is therefore respectfully submitted that Durham and Lawes, taken alone or in any combination, do not teach or suggest a sliding sleeve with a “central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve,” as recited in claim 19 and that claim 19 is therefore allowable. Because claims 20 - 25, 27, 31 and 34 - 36 depend from and therefore include all of the limitations of claim 19, it is respectfully submitted that these claims are also allowable.

Claim 37 recites limitations substantially similar to those of claim 19 including “a sliding sleeve having a central bore, a *circular interior surface profile*, and a non-circular exterior surface profile” in combination with a “*shaft configured and dimensioned for free rotation within the central bore of the sliding sleeve.*” Therefore, it is respectfully submitted that claim 37 is also allowable over Durham and Lawes for at least the same reasons previously mentioned with regard to claim 19. Because claims 38 and 40 depend from and therefore contain all the limitations of claim 37, it is respectfully submitted that these claims are also allowable.

Claim 27 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Durham in view of Lawes and in further view of U.S. Patent No. 6,648,889 to Bramlet et al.

Claim 27 depends from and therefore includes all of the limitations of claim 19. As discussed above, Durham and Lawes fail to teach or suggest a sliding sleeve with a “central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve,” as recited in claim 19. It is further submitted that Bramlet fails to cure the above-noted deficiency of Durham and

Lawes. It is therefore submitted that Durham, Lawes and Bramlet, taken alone or in any combination, fail to teach or suggest the recited limitations of claim 19. Because claim 27 depends from and therefore includes all of the limitations of claim 19, it is respectfully submitted that this claim is also allowable.

Claims 28 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Durham in view of Lawes and in further view of U.S. Patent No. 4,432,358 to Fixel.

Claims 28 and 29 depend from and therefore include all of the limitations of claim 19. As discussed above, Durham and Lawes fail to teach or suggest a sliding sleeve with a “central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve,” as recited in claim 19. It is further submitted that Fixel fails to cure the above-noted deficiency of Durham and Lawes. It is therefore submitted that Durham, Lawes and Fixel, taken alone or in any combination, fail to teach or suggest the recited limitations of claim 19. Because claims 28 and 29 depend from and therefore include all of the limitations of claim 19, it is respectfully submitted that these claims are also allowable.

Claims 30, 32 and 39 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Durham in view of Lawes and in further view of U.S. Patent No. 5,908,422 to Bresina.

Claims 30 and 32 and claim 39 depend from and therefore include all of the limitations of claims 19 and 37, respectively. As discussed above, Durham and Lawes fail to teach or suggest a sliding sleeve with a “central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve,” as recited in claim 19 and “a circular interior surface profile, and a non-circular exterior surface profile” in combination with a “shaft configured and dimensioned for free rotation within the central bore of the sliding sleeve,” as recited in claim 37. It is further

submitted that Bresina fails to cure the above-noted deficiencies of Durham and Lawes. It is therefore submitted that Durham, Lawes and Bresina, taken along or in any combination, fail to teach or suggest the recited limitations of claims 19 and 37. Because claims 30 and 32 and claim 39 depend from and therefore includes all of the limitations of claims 19 and 37, respectively, it is respectfully submitted that these claims are also allowable.

Claim 33 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Durham in view of Lawes in further view of Bresina and in further view of U.S. Patent No. 6,187,007 to Frigg et al.

Claim 33 depends from and therefore includes all of the limitations of claim 19. As discussed above, Durham and Lawes fail to teach or suggest a sliding sleeve with a “central bore and interior surface profile configured to receive the shaft of the bone fixation element while permitting free rotation of the bone fixation element relative to the sleeve,” as recited in claim 19. It is further submitted that Bresina and Frigg fail to cure the above-noted deficiency of Durham and Lawes. It is therefore submitted that Durham, Lawes, Bresina and Frigg, taken alone or in any combination, fail to teach or suggest the recited limitations of claim 19. Because claim 33 depends from and therefore includes all of the limitations of claim 19, it is respectfully submitted that this claim is also allowable.

In light of the foregoing, Applicants respectfully submit that all of the pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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